DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 4, 2014

Rhinix Aps
% Ms. Mette Munch
QA Consultant
Otto Ruds Gade 34, 2th
DK-8200 Aarhus N
Denmark

Re: K134003
Trade/Device Name: Rhinix™ nasal filter
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical recirculating air cleaner
Regulatory Class: Class II
Product Code: NUP
Dated: July 8, 2014
Received: August 7, 2014

Dear Ms. Munch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina Eydelman
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K134003

Device Name
Rhinix™ nasal filter

Indications for Use *(Describe)*

RHINIX™ nasal filter for patients aged 6 years and older, with properties that allow unimpeded nasal breathing, is for the prevention or alleviation of seasonal allergic rhinitis (hay fever) and for seasonal or perennial allergies to other airborne allergens with a similar size fraction to grass pollen allergens.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) summary – Rhinix™ nasal filter

Administrative information:


| | |
|---|---|
| Name: | Rhinix Aps |
| Address: | Otto Ruds Gade 34, 2th |
| | DK-8200 Aarhus N |
| | Denmark |
| Contact person: | Mette Munch, QA Consultant |
| Cell phone: | +45 29872000 |
| E-mail: | mm@addaction.dk |


Date of summary: 29-Aug-2014

Name of device:

Trade name: Rhinix Nasal Filter
Common name: Nasal filter
Classification name: Recirculating Air Filter (NUP)

Predicate devices:

| 510(k) or reg. no | Manufacturer | Device | Product Code |
|---|---|---|---|
| K120894 | HayMax™ Limited, Bedfordshire, UK | Haymax™ Organic Drug-Free Pollen Barrier Balm | NUP |
| 3007479155 | Sam Joung International | Nosk Nose Filters | LWF |
| 3007279871 | Airware Holdings | Air Allergy Advanced Nasal Filter | LWF |

Device description:

The device consists of a filtering membrane/media and a frame. The filtering membrane is a planar filter made of polypropylene non-woven fibers. The frame is made of medical grade SEBS compound which is a biocompatible polymer designed for human skin contact. Each filter section in each nostril is connected via the frame's u-shaped bridge. The device is made in multiple sizes.

The device is inserted in the nostrils and is in contact with unbroken skin in the anterior vestibule of the nostrils (non-invasive). The device functions as a filtering device (mechanical barrier) that removes particles (pollen) from the inhaled air. The filter allows adequate air movement while breathing through the nose. The device is single-use and should only be used when exposed to allergens.

Intended use:

Rhinix™ nasal filter for patients aged 6 years and older, with properties that allow unimpeded nasal breathing, is for the prevention or alleviation of seasonal allergic rhinitis (hay fever) and for seasonal or perennial allergies to other airborne allergens with a similar size fraction to grass pollen allergens.

Comparison to Predicate Device:

Table 1: Comparison between Rhinix™ nasal filter and K120894 – Haymax™ with respect to intended use:

| | **Rhinix™ nasal filter** | **K120894 – Haymax™** |
|---|---|---|
| *Intended use* | Rhinix™ nasal filter for patients aged 6 years and older, with properties that allow unimpeded nasal breathing, is for the prevention or alleviation of seasonal allergic rhinitis (hay fever) and for seasonal or perennial allergies to other airborne allergens with a similar size fraction to grass pollen allergens. | HayMax™ is intended to promote alleviation of mild allergic symptoms (i.e. mild nasal irritation, including itchy, runny, or congested nasal passages), triggered by the inhalation of various airborne allergens including grass and tree pollen, house dust mite and animal dander. It is intended to be used by anyone who experiences symptoms of hayfever or allergic rhinitic. As it is drug-free and organic it is also considered suitable for children or pregnant women. |

Summary of technical characteristics of device compared to predicate devices:
Rhinix™ nasal filter and Haymax™ Pollen Barrier Palm achieve their intended use based on a similar principle, which is to introduce a barrier that reduces the pollen load in the nasal cavity. Haymax™ Pollen Barrier Palm achieves this using a drug free topical viscous balm applied around the nasal cavity. Rhinix™ achieves its intended use with a membrane just inside the entrance to the nasal cavity. It has been shown in bench tests that the membrane used in a Rhinix™ nasal filter has an airflow resistance below the level of perception. It has also been shown in bench tests that a Rhinix™ Nasal Filter membrane removes particles with a similar size distribution to pollens from the air stream. They are both provided non-sterile, non-prescriptive for over-the-counter use.

The comparison between Rhinix™ nasal filter and Nosk Nose Filter and Air Allergy Advanced Nasal Filter, respectively, is illustrated in figure 1 below. The comparison relates especially to the general design elements of the products. They all consist of three essential parts: a frame, a membrane and a connecting u-shaped bridge. Their contact with the nasal cavity is also equivalent as they all have to be inserted into the nostrils. Nosk Nose filters and Rhinix™ Nasal Filters both use a polypropylene membrane, which is non-toxic. The intended use of Nosk Nose Filter and Air Allergy Advanced Filter is as a nasal dilator, which is different from the intended use of the Rhinix™ Nasal Filter. This difference in intended use does not influence the safety of Rhinix™ when compared to Nosk Nose filter and Air Allergy Advanced Filter and does not influence the effectiveness of Rhinix™ in being placed in the anterior nasal cavity similar to the predicate devices. Rhinix™ uses a membrane that allows unimpeded breathing and that removes pollens sufficiently to reduce allergy symptoms (see below for clinical data).

**Fig 1:** Comparison of Rhinix™ nasal filters with two LWF devices.
Left: Nosk Nose Filters (Sam Joung International, reg no. 3007479155).
Middle: Air Allergy Advanced Nasal Filer (Airware Holdings, reg. no. 3007279871)
Right: Rhinix™ Nasal Filter.

Predicate devices and Rhinix™ Nasal Filter do not contain software and do not require EMC and Electrical Safety evaluation.

Summary of substantial equivalence based on clinical data
Haymax™ Pollen Barrier Palm has been cleared for the intended use of alleviation of seasonal

allergic rhinitis. The clinical trial (NCT01699165) reported in the Journal of Allergy and Clinical Immunology titled "*Nasal filters for the treatment of allergic rhinitis: A randomized, double-blind, placebo-controlled crossover clinical trial"* demonstrated that Rhinix™ significantly reduced daily symptoms of hay fever as measured by total TNSS (p=0,049). Sneezing, itching and rhinorrhea, as well as throat irritation were also significantly reduced compared to placebo. The study also showed that there was no difference in perception of increased nasal resistance when wearing Rhinix™ compared to a placebo device, and Rhinix™ could thus be considered to allow unimpeded breathing. Finally, the study indicated that a Rhinix™ Nasal Filter is safe to use.

Thus, based on the intended use of providing alleviation of seasonal allergic rhinitis, Rhinix™ is substantial equivalent to the predicate device Haymax™ Pollen Barrier Palm.

Conclusion on substantial equivalence based on technical comparison and clinical data:

Rhinix™ Nasal Filters pose no safety threat or health risk to users and has been demonstrated demonstrated to reduce symptoms related to seasonal allergic rhinitis and work as intended. Because of the physical/mechanical mode of action there are no known interactions with other medicines and it can be safely used complimentary to other forms of treatment of allergic rhinitis.

Thus, by virtue of the physical characteristics and intended use, the Rhinix™ nasal filter is substantially equivalent to devices legally cleared to be marketed in the United States.

Verification of Summary:

Rhinix ApS can verify that the summary includes only information that is also covered in the body of the 510(k). The summary does not contain any puffery or unsubstantiated labeling claims. The summary does not contain any raw data only summary data. The summary does not contain any trade secret or confidential commercial information. The summary does not contain any patient identification information.